

(3) “Overuse of this product may produce increased redness of the eye.”

(4) “If solution changes color or becomes cloudy, do not use.”

(5) “When using this product [in bold type] pupils may become enlarged temporarily.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

[53 FR 7090, Mar. 4, 1988, as amended at 65 FR 38428, June 21, 2000]

**§ 349.78 Labeling of eyewash drug products.**

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: “eyewash,” “eye irrigation,” or “eye irrigating solution.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” one of the following phrases:

(1) “For” (select one of the following: “flushing,” “irrigating,” “cleansing,” “washing,” or “bathing”) “the eye to remove” (select one or more of the following: “loose foreign material,” “air pollutants (smog or pollen),” or “chlorinated water”).

(2) “For” (select one of the following: “flushing,” “irrigating,” “cleansing,” “washing,” or “bathing”) “the eye to help relieve” (select one or more of the following: “irritation,” “discomfort,” “burning,” “stinging,” “smarting,” or “itching”) “by removing” (select one or more of the following: “loose foreign material,” “air pollutants (smog or pollen),” or “chlorinated water”).

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading “Warnings” for all eyewash products:

(1) “If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.”

(2) “Obtain immediate medical treatment for all open wounds in or near the eyes.”

(3) “If solution changes color or becomes cloudy, do not use.”

(d) *Directions.* The labeling of the product contains the following information

under the heading “Directions”:

(1) *For eyewash products intended for use with an eyecup.* Rinse cup with clean water immediately before each use. Avoid contamination of rim and inside surfaces of cup. Fill cup half full and apply the cup to the affected eye, pressing tightly to prevent the escape of the liquid, and tilt the head backward. Open eyelids wide and rotate eyeball to ensure thorough bathing with the wash or lotion. Rinse cup with clean water after each use.

(2) *For eyewash products intended for use with a nozzle applicator.* Flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle.

[53 FR 7090, Mar. 4, 1988, as amended at 68 FR 7921, Feb. 19, 2003]

**§ 349.79 Labeling of permitted combinations of active ingredients.**

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part.

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the indication(s) for each ingredient in the combination, as established in the indications sections of this part.

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings sections of this part.

(d) *Directions.* The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of this part. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

#### § 349.80 Professional labeling.

The labeling of any OTC ophthalmic demulcent drug product provided to health professionals (but not to the general public) may contain instructions for the use of these products in professional eye examinations (i.e. gonioscopy, electroretinography).

### PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

#### Subpart A—General Provisions

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350.1 Scope.  
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#### Subpart B—Active Ingredients

350.10 Antiperspirant active ingredients.

#### Subpart C—Labeling

350.50 Labeling of antiperspirant drug products.

#### Subpart D—Guidelines for Effectiveness Testing

350.60 Guidelines for effectiveness testing of antiperspirant drug products.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 34291, June 9, 2003, unless otherwise noted.

#### Subpart A—General Provisions

##### § 350.1 Scope.

(a) An over-the-counter antiperspirant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general

condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

##### § 350.3 Definition.

As used in this part:

*Antiperspirant.* A drug product applied topically that reduces the production of perspiration (sweat) at that site.

#### Subpart B—Active Ingredients

##### § 350.10 Antiperspirant active ingredients.

The active ingredient of the product consists of any of the following within the established concentration and dosage formulation. Where applicable, the ingredient must meet the aluminum to chloride, aluminum to zirconium, and aluminum plus zirconium to chloride atomic ratios described in the U.S. Pharmacopeia-National Formulary. The concentration of ingredients in paragraphs (b) through (j) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in an aerosol or nonaerosol dosage form. The concentration of ingredients in paragraphs (k) through (r) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in a nonaerosol dosage form. The labeled declaration of the percentage of the active ingredient should exclude any water, buffer components, or propellant.

(a) Aluminum chloride up to 15 percent, calculated on the hexahydrate form, in an aqueous solution nonaerosol dosage form.

(b) Aluminum chlorohydrate up to 25 percent.

(c) Aluminum chlorohydrate polyethylene glycol up to 25 percent.

(d) Aluminum chlorohydrate propylene glycol up to 25 percent.

(e) Aluminum dichlorohydrate up to 25 percent.

(f) Aluminum dichlorohydrate polyethylene glycol up to 25 percent.

(g) Aluminum dichlorohydrate propylene glycol up to 25 percent.